In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: September 29, 2023

LORRIE JONES, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 17-1890V Special Master Sanders

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Mitchell Jones, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On December 6, 2017, Lorrie Jones ("Petitioner") filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2018),[2] alleging "injuries, including Shoulder Injury Related to Vaccine Administration ("SIRVA"), resulting from adverse effects of a tetanus/diphtheria ("Tdap") vaccination she received on October 25, 2016." Pet. at 1, ECF No. 1. After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has failed to provide preponderant evidence that the Tdap vaccine she received on October 25, 2016, caused her to suffer from a Table SIRVA. However, I do find preponderant evidence that Petitioner suffered

[1] Because this Ruling contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

from an off-Table local shoulder injury consistent with SIRVA. Accordingly, Petitioner is entitled to compensation.

I. Procedural History

Due to Petitioner's SIRVA allegation, Petitioner's case was originally assigned to the chief special master and the special processing unit. ECF No. 4. Petitioner filed a notice of intent to file on compact disc ("CD") and her statement of completion on December 18, 2017. ECF Nos. 7–8. The CD contained Petitioner's proof of vaccination, medical records, and a personal affidavit. Pet'r's Exs. 1–7. On February 13, 2018, Petitioner filed a supplemental affidavit, her vaccine consent form, and a second statement of completion. Pet'r's Exs. 8–9, ECF No. 10; ECF No. 11. Respondent filed his Rule 4(c) Report arguing that compensation is not appropriate in this case on November 1, 2018. Resp't's Report at 1, ECF No. 20. Petitioner filed an additional medical record on January 4, 2019. Pet'r's Ex. 10, ECF No. 22-1. On January 13, 2019, Petitioner filed a second supplemental affidavit and her VAERS report. Pet'r's Exs. 11–12, ECF No. 24. Respondent filed a status report on March 25, 2019, indicating his intention to continue to defend against Petitioner's claim. ECF No. 26. The case was reassigned to me on April 9, 2019. ECF No. 28.

Petitioner filed three witness affidavits on August 11, 2019. Pet'r's Exs. 13–15, ECF No. 32. On September 9, 2019, Petitioner filed her first expert report from Clifford Colwell, Jr., M.D., Dr. Colwell's C.V., and Dr. Colwell's biography. Pet'r's Exs. 16–18, ECF No. 34. Respondent filed his first expert report from Paul Cagle, M.D. on May 1, 2020. Resp't's Ex. A, ECF No. 40-1. On September 8, 2020, Petitioner filed her first supplemental expert report from Dr. Colwell, along with medical literature. Pet'r's Exs. 19–24, ECF No. 44. Respondent filed his first supplemental expert report from Dr. Cagle on January 11, 2021. Resp't's Ex. B, ECF No. 45-1. Petitioner filed an expert report from Uma Srikumaran, M.D. on March 29, 2021, along with medical literature. Pet'r's Exs, 25–36, ECF No. 46. Respondent responded with a second supplemental report from Dr. Cagle on August 24, 2021. Resp't's Ex. C, ECF No. 49-1. On November 29, 2021, Petitioner filed a supplemental expert report from Dr. Srikumaran, along with his C.V. and medical literature. Pet'r's Exs. 37–42, ECF No. 50. Respondent indicated via email on February 10, 2022, that he did not intend to file an additional expert report. Informal Comm., docketed Feb. 11, 2022.There have been no further submissions from either party.

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. 300aa § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). Accordingly, this matter is now ripe for resolution.

II. Factual History

A. Medical Records

1. Pre-vaccination Medical Records

Petitioner presented to her primary care provider ("PCP"), Ashleigh Brooke Teates, N.P., on May 13, 2016 to establish care. Pet'r's Ex. 4 at 7. The record from that visit includes a medical history of hypothyroidism, seizures, migraines, chronic pain- fibromyalgia,[4] GERD, and depression/anxiety. *Id*. Petitioner also had spinal fusion surgery in 2007. *Id.* N.P. Teates assessed Petitioner with unspecified hypothyroidism, fatigue, Vitamin D deficiency, dysthymic disorder, migraines, and insomnia. *Id.* at 9.

2. Vaccination and Post-Vaccination Medical Records

On October 25, 2016, Petitioner received the Tdap vaccine at issue in this case in her left shoulder. Pet'r's Ex. 1 at 1. She also received influenza and pneumococcal conjugate vaccines in her right shoulder. *Id.* She was fifty-one years old at the time of her vaccinations. *Id.*

Petitioner's first medical visit post vaccination was with her PCP on November 15, 2016. Pet'r's Ex. 2 at 3. She was seen for routine lab work based on her medical history and did not mention shoulder pain or any other acute complaints. *See id.* at 3–4.

On December 1, 2016, Petitioner saw neurologist Michael Becker, M.D. with chief complaints of migraine without aura and generalized convulsive epilepsy. Pet'r's Ex. 5 at 1. Specifically, Petitioner reported worsening headaches "the past [four to five] months," that manifest every two weeks as throbbing and pressure. *Id.* at 3. Petitioner also reported that her fibromyalgia manifested as "[three]-day flare-ups of pain once every [four] weeks lately." *Id.* She described "[four] episodes of pain and tingling going up to the neck to the base of her skull, and also in the lower back during flare-ups[.]" *Id.* The medical record contains a detailed list of potential concerns. *See id.* Of note, Petitioner reported fatigue, nausea or vomiting, muscle pain or cramps and back pain. *Id.* She reported "no joint pain, no joint stiffness, no weakness of muscles or joints, [and] no cold extremities[.]" *Id.* Upon exam, Dr. Becker noted "[c]ervical Spine: no tenderness and decreased [range of motion ("ROM")] (mildly on lateral rotation to either side)." *Id.* at 4. An extensive motor exam included the following left upper extremity findings: normal motor strength, abduction 5/5, internal rotation 5/5, and external rotation 5/5. *Id.*

Petitioner saw orthopedist Donnis Harrison, M.D. approximately three months post vaccination on January 26, 2017. Pet'r's Ex. 2 at 5. Petitioner self-referred with complaints of constant aching and throbbing in her left shoulder that was mild to moderate in severity but that "[was] aggravated by range of motion and certain movements." *Id.* She reported that her "shoulder pain began after receiving the TDAP immunization." *Id.* Petitioner further reported nonspecific joint pain, joint swelling, muscular weakness, muscle pain, back pain, and limitation of motion. *Id.* at 7. Upon inspection, Petitioner's left shoulder was "tender[ ] to palpation over lateral aspect deltoid[,]" and she exhibited evidence of "pain with abduction past 90 degrees, active internal rotation: limited to sacrum, active forward elevation: > 150 degrees, [and] active external rotation: 45 to 65 degrees." *Id.* Neer and Hawkins tests both also yielded positive results. *Id.* Dr. Harrison

[4] Fibromyalgia is "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." *Dorland's Illustrated Medical Dictionary* 696 (33rd ed. 2020) [hereinafter "*Dorland's*"].

assessed Petitioner with "[i]mpingement syndrome[5] of shoulder, left." *Id.* at 8. Petitioner was given a steroid injection and prescribed physical therapy. *Id.*

On January 31, 2017, Petitioner began physical therapy with Erin Moody, P.T. Pet'r's Ex. 3 at 889. Petitioner reported to P.T. Moody that she first experienced "pain in the left shoulder following an injection she received by her pharmacy on October 25, 2016." *Id.* She explained that the "pain and stiffness gradually progressed so she made an appointment with [an orthopedist]." *Id.* Petitioner noted that the steroid injection she received from Dr. Harrison helped, and P.T. Moody provided her with a home exercise plan. *Id.* at 889–890. During an emergency room visit on April 22, 2017, for unrelated bladder pain and diarrhea, Petitioner was noted to have "[g]ood range of motion in all major joints." *Id.* at 775, 778.

Petitioner returned to Dr. Harrison approximately five months after her evaluation with P.T. Moody, on June 13, 2017. Pet'r's Ex. 2 at 17. Petitioner complained of renewed and more severe pain, following the month of relief that the steroid injection and physical therapy had provided. *Id.* She described the pain as "radiating into her neck and down into her elbow." *Id.* Dr. Harrison administered a second steroid injection. *Id.* at 19–20. He also ordered an MRI, which showed "[m]oderate supraspinatus tendinosis[6] with a chronic low-grade partial thickness bursal[7] surface tear through the proximal supraspinatus tendon," as well as mild-to-moderate acromioclavicular ("AC") joint[8] osteoarthrosis,[9] moderate intra-articular biceps tendinosis, mild glenohumeral arthrosis, and small joint effusion. *Id.*

Dr. Harrison saw Petitioner on July 7, 2017, for follow up in light of her MRI results. *Id.* at 27. He diagnosed her with impingement syndrome of the left shoulder, osteoarthritis of the left shoulder and AC joint, and an incomplete tear of the left rotator cuff. *Id.* at 29. On July 25, 2017, Dr. Harrison surgically repaired Petitioner's left rotator cuff partial thickness tear. *Id.* at 31–32. He also performed extensive debridement of the bursal surface rotator cuff, as well as a distal clavicle resection and subacromial decompression with a partial acromioplasty.[10] *Id.* at 31. The operative report noted that "a complete bursectomy[11] was performed[.]" *Id.* at 32.

On August 1, 2017, Petitioner was seen by Rachel Hines, P.T., for a physical therapy evaluation to rehabilitate her shoulder after surgery. Pet'r's Ex. 6 at 1. Petitioner reported that

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[5] Impingement syndrome is "a type of overuse injury with progressive pathologic changes resulting from mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff[.]" *Dorland's* at 1804. The rotator cuff is "a musculotendinous structure about the capsule of the shoulder joint[.]" *Id.* at 436.

[6] Tendinosis, or tendinopathy, is "any pathologic condition of a tendon[.]" *Dorland's* at 1852.

[7] A bursa is "a sac or saclike cavity filled with a viscid fluid and situated at places in the tissues at which friction would otherwise develop." *Dorland's* at 258.

[8] The AC joint is "the synovial joint between the acromion of the scapula and the acromial extremity of the clavicle[.]" *Dorland's* at 156.

[9] Osteoarthrosis, or osteoarthritis, is "a noninflammatory degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane." *Dorland's* at 1326.

[10] Acromioplasty is "surgical removal of an anterior spur of the acromion to relieve mechanical compression of the rotator cuff during movement of the glenohumeral joint[.]" *Dorland's* at 20.

[11] A bursectomy is "excision of a bursa." *Dorland's* at 260.

her shoulder pain began after receiving a vaccine in October of 2016. *Id.* Petitioner returned to Dr. Harrison on August 14, 2017, for a post-surgery follow-up. Pet'r's. Ex. 2 at 34. She complained of increased left shoulder pain and numbness radiating down her arm. *Id.* Petitioner was prescribed a Medrol[12] dose pack and advised to alter her activity. *Id.* at 36. Dr. Harrison believed that Petitioner's ulnar nerve may have been irritated by her sling. *Id.* He advised Petitioner to follow up in two months. *Id.* On October 5, 2017, Petitioner completed physical therapy. Pet'r's Ex. 6 at 51. Her discharge record noted that she was no longer functionally limited and was able to complete all of her movements without deviation and all activities of daily living with good strength. *Id.* at 51–52.

B. Affidavits

Petitioner filed three personal affidavits in this case. Pet'r's Exs. 7, 8, 11. In her initial November 10, 2017 affidavit, Petitioner described "enormous pain in the area [of her upper left shoulder] where [her vaccine] was injected." Pet'r's Ex. 7 ¶ 1. She wrote that she thought the pain would go away in time, but "hours turned into days, then weeks[,] and then months." *Id.* Petitioner described her appointment with Dr. Harrison on January 26, 2017. *Id.* ¶ 2. Despite the steroid injection and physical therapy exercises, "the pain became worse[,] and [she] experienced weakness, throbbing and some numbness." *Id.* After several months, Petitioner made another appointment for June 13, 2017, which ultimately led to shoulder surgery. *Id.* ¶ 3. Petitioner described physical therapy following her surgery and noted that it helped a lot before she was discharged. *Id.* ¶ 5. She noted that her shoulder continued hurting sometimes, but she said before the surgery, she "could not do any of [her] daily duties in the house." *Id.* ¶ 6. Petitioner explained that she could not "cook, clean, do the laundry, raise [her] arms to put on clothes/bra, wash [her] hair, get into or out of [her] bathtub, or do the dishes." *Id.* She continued that she is responsible for the care of her disabled son. *Id.* Petitioner "know[s] that [her] shoulder will never be 100 percent[, and she was still] unable to "reach all the way behind [her] back." *Id.* She stated that because of her pre-existing fibromyalgia, "the pain from her shoulder had a huge impact on [her]." *Id.* ¶ 7.

Petitioner signed her second affidavit on January 12, 2018. Pet'r's Ex. 8 at 1, ECF No. 10-1. She explained that she intentionally did not express to Dr. Becker, her neurologist, that she was experiencing shoulder pain on December 21, 2016. *Id.* ¶ 1. This was "[b]ecause shoulders are not Dr. Becker's area of expertise." *Id.* She added that he "only treats [her] for [her] problems concerning neurology issues." *Id.*

In Petitioner's third affidavit, signed January 13, 2019, she reiterated that she felt "intense pain" at the time of the injection. Pet'r's Ex. 11 ¶ 1, ECF No. 24-1. She continued that "[b]y the next day the pain was so severe that [she] felt like [her] arm was about to fall off." *Id.* Petitioner noted that she has "several serious medical conditions that are unrelated to the pain in [her] left shoulder." *Id.* ¶ 2. She noted that the record from her November 15, 2016 PCP appointment does not mention the pain from her left shoulder or the "several of the other chronic medical conditions [she] suffered from." *Id.* Petitioner wrote:

> The lack of notes related to [her] shoulder should not be interpreted as [her] not having shoulder pain at that time. The fact is that [her] pain was severe and intense.

[12] Medrol, or methylprednisolone, is a synthetic glucocorticoid. *Dorland's* at 1137.

> By the next day after receiving the shot, [she] was unable to lift or move [her] arm at all without pain. The pain was so bad that on December 27, 2016, [she] filed a VAERS report.

Id. Petitioner's VAERS report has an adverse event onset date of October 26, 2016. *Id.*; Pet'r's Ex. 12 at 1, ECF No. 24-2. She stated that she filed the report because she wanted to "notify someone in the government about the debilitating pain that the shot had caused." Pet'r's Ex. 11 ¶ 2. She stated that she "filed that VAERS report long before [she] ever knew anything about filing a claim in the Vaccine Program." *Id.*

Petitioner also provided additional information about her December 2016 visit to Dr. Becker. *Id.* ¶ 3. She explained that appointments with Dr. Becker are typically limited to fifteen minutes, and she "did not want to burden [him] with [her] shoulder, especially when [she] was there to be seen for other serious conditions." *Id.* Petitioner conceded that the record notes she did not have joint pain. *Id.* She explained that "[t]he pain in [her] shoulder was never mentioned during [their] time together, and Dr. Becker did not conduct an examination of [her] left shoulder on that day." *Id.*

In addition to Petitioner's personal affidavits, she submitted affidavits from her husband, signed April 2, 2019, and her mother and sister, signed April 12, 2019. Pet'r's Exs. 13–15. All three of the affidavits focus on the onset of Petitioner's pain. *See id.* Petitioner's husband, Lt. Col. Daniel Jones, recounted a phone call he received on October 25, 2016, during which Petitioner described extreme pain in her left arm, immediately post vaccination. Pet'r's Ex. 13 at 1, ECF No. 32-1. Petitioner also told him that the vaccination site in her left arm was higher than the one in her right. *Id.* Lt. Col. Jones remembered that it was hurricane season, a busy time for him, and he was concerned about her ability to manage without him. *Id.* He noted that "[s]he still does home physical therapy because she still has some minor issues, . . . [b]ut, that excruciating pain was fixed with the surgery." *Id.* He stated that his wife's "shoulder was fine before she went to receive these vaccines." *Id.*

Petitioner's mother's affidavit was brief. *See* Pet'r's Ex. 14 at 1, ECF No. 32-2. Petitioner's mother, Linda Langston, "verif[ied] that [Petitioner] called [her] on October 25, 2016, and told [her] about the events that took place earlier in the day." *Id.* Petitioner told her that the pain was immediate and excruciating. *Id.* Ms. Langston remembered that she and Petitioner discussed that they "had just celebrated [Ms. Langston's] birthday the weekend prior and that is was a good thing that [Petitioner] waited to get the vaccines until afterward." *Id.* Petitioner's mother said that "[P]etitioner ha[d] never complained with shoulder pain before." *Id.* She added that Petitioner "explained her pain [as] the worst she[had] ever experienced." *Id.*

Lana Hardwick is Petitioner's sister, and she provided the third witness affidavit. Pet'r's Ex. 15 at 1, ECF No. 32-3. Ms. Hardwick also stated that Petitioner called her on the date of her vaccination, October 25, 2016, complaining of terrible pain in her left arm after the shot. *Id.* She recalled that Petitioner was hopeful the pain would resolve on its own. *Id.* Ms. Hardwick related the dated back to "three days after [her] mother's birthday." *Id.* She noted that her "sister was forced to undergo a painful shoulder surgery and go through a painful recovery that included physical therapy which was not easy on her." *Id.* Ms. Hardwick also stated that Petitioner did not have left shoulder problems prior to her vaccination and that Petitioner told her that the Tdap

vaccine was given higher up on her left arm than the vaccines administered in Petitioner's right arm the same day. *Id.*

III. Expert Reports

A. Petitioner's Expert, Clifford W. Colwell, Jr., M.D.

Clifford W. Colwell, Jr., M.D., is a board-certified orthopaedic surgeon, who received his undergraduate degree from Williams College and his medical degree from the University of Michigan. Pet'r's Ex. 17 at 1, 3, ECF No. 34-2. Dr. Colwell's postdoctoral training includes an internship and general surgery residency at the University of Michigan, followed by a residency in orthopaedic surgery at the Hospital for Special Surgery in New York and a trauma fellowship at Los Angeles County Hospital. *Id.* at 1. He currently serves as the medical director of the Shiley Center for Orthopaedic Research and Education at Scripps Clinic in California, as a clinical professor at the University of California, San Diego School of Medicine in the Department of Orthopaedics and Rehabilitation, and as an adjunct clinical professor at The Scripps Research Institute in the Department of Basic Science and Clinical Research. *Id.* at 2. Previously, Dr. Colwell was chief of the Orthopaedic Division at Scripps Clinic and Director of the Lower Extremity Reconstruction Fellowship Program, and he was also the team physician for the San Diego Padres. Pet'r's Ex. 16 at 1, ECF No. 34-1. During this time, he treated numerous professional athletes for "severe shoulder injuries requiring both extensive diagnostic testing as well as non-surgical and surgical treatment modalities." *Id.*

After review of Petitioner's medical record, Dr. Colwell concluded that Petitioner "meets the defined definitions of SIRVA, as outlined by the Vaccine Injury Compensation Program[.]" *Id.* He did not find any "indication that [Petitioner] had any previous history of left shoulder pain, inflammation, or dysfunction of the affected shoulder prior to her [Tdap] vaccination on October 25, 2016[,]" in Petitioner's medical records. *Id.* Dr. Colwell acknowledged that Petitioner did not complain to a medical provider until "about three months" post vaccination; however, he opined "that her shoulder pain began within 48 hours" of her vaccination. *Id.* He noted that "all medical records that address the issue of onset consistently note that [Petitioner's] shoulder pain began when she received her [Tdap] vaccine on October 25, 2016." *Id.* at 2. Dr. Colwell also relied on Petitioner's December 27, 2016 VAERS report and witness affidavits, which Dr. Colwell described as "entirely consistent with the medical records and indicate that [Petitioner's] pain began when she received the [Tdap] vaccine." *Id.* Continuing through the Table SIRVA requirements, Dr. Colwell did not believe that a single complaint of non-specific pain that radiated to Petitioner's neck and elbow on June 13. 2017, was in any way related to her diagnosed left shoulder impingement. *Id.* Petitioner's symptom improvement following a cortisone shot and then shoulder surgery provided further evidence to Dr. Colwell that her injury was consistent with SIRVA. *Id.* Dr. Colwell finally noted that "no other condition or abnormality is present that would explain [Petitioner's] symptoms." *Id.* at 3.

In Dr. Colwell's supplemental expert report, he reiterated his conclusion that Petitioner meets the four criteria for a Table SIRVA. Pet'r's Ex. 19 at 1, ECF No. 44-1. However, he supplemented his opinion regarding the nature of Petitioner's Table SIRVA symptom onset and injury and provided a biological mechanism for an off-Table vaccine-related shoulder injury. Dr.

Colwell opined that Petitioner's June 2017 "MRI showed evidence of moderate supraspinatus tendinosis, a partial thickness rotator cuff tear, and biceps tendinosis, all consistent with a Table SIRVA injury." *Id.* at 2. Discussing causation-in-fact, Dr. Colwell cited a 2010 Atanasoff et al.[13] article that "provides support for the theory that antigenic material from the vaccine that is injected into synovial tissues results in an immune mediated inflammatory reaction." *Id.* (citing Pet'r's Ex. 21 at 1, ECF No. 44-3). Dr. Colwell also cited the Bodor and Montalvo[14] article that found an inflammatory post-vaccination response in two patients caused shoulder pain. *Id.* at 3 (citing Pet'r's Ex. 20, ECF No. 44-2). The authors "hypothesize that in both of [their] two cases, vaccine was injected in the subdeltoid bursa[, which is] contiguous with the subacromial bursa [and] led to subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." Pet'r's Ex. 20 at 2. They cautioned against vaccinations "in the upper third of the deltoid muscle," and they identified subacromial bursitis, bicipital tendonitis, and adhesive capsulitis as consistent a diagnosis of "vaccination-related shoulder dysfunction." *Id.* at 3. Dr. Colwell cited the Institute of Medicine,[15] which concluded that "[t]he evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis." Pet'r's Ex. 19 at 3 (citing Pet'r's Ex. 22 at 7, ECF No. 44-4).

Although Dr. Colwell maintained that Petitioner suffered from a Table SIRVA, he noted that "[a] very recent investigation by Hesse et al[.],[16] a large case series based on Vaccine Program claims, adds further support and reliability to the general theory of causation of SIRVA." *Id.* (citing Pet'r's Ex. 24, ECF No. 44-6). The investigation identified post-vaccination, musculoskeletal injuries that present as shoulder pain, "followed by rotator cuff problems and bursitis. Common findings on MRI included tendonitis/osis/inopathy, rotator cuff tears and bursitis." Pet'r's Ex. 24 at 6. The authors concluded that these injuries, in the case of "true SIRVA is likely preventable." *Id.* Vaccine administrators were advised that "care should be taken to ensure that the injection is placed in the thick, centrally located portion of the deltoid muscle, away from the upper third of the deltoid where the risk of over penetration in the underlying structures of the shoulder is greatest." *Id.* at 6–7.

Dr. Colwell further noted that the Atanasoff article "indicated onset could be as late as 4 days after vaccination[,] and Arias stated onset could be as delayed as much as 7-60 days after vaccination." Pet'r's Ex. 19 at 2. Specifically the Atanasoff article reported pain onset "as occurring less than 24 h after vaccination in 93% and occurred immediately following injection in 53% of [cases.]" Pet'r's Ex. 21 at 2. Arias et al.[17] noted a latency period for six of eight patients with "increasing severity [of] pain starting within the first 24 h or few days (4-7 days) post-vaccination, and 2 reported pain within 2 months." Pet'r's Ex. 23 at 3, ECF No. 44-5. They also noted that patients experienced pain "of increasing severity" over time. *Id.* In conclusion, Dr.

[13] S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8049 (2010).
[14] Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction*, 25 VACCINE 585 (2007).
[15] K. Stratton et al. (eds.), Institute of Medicine, *Adverse Effects of Vaccines, Evidence and Causality*, 618 (2012).
[16] Elizabeth M. Hesse et al., *Shoulder Injury Related to Vaccine Administration ("SIRVA"): Petitioner claims to the National Vaccine Injury Compensation Program, 2010–2016*, 38 VACCINE 1076 (2020).
[17] L.H. Martín Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations*, 35 VACCINE 4870 (2017).

Colwell reiterated that he "believe[s Petitioner's] onset was within 48 hours of vaccination, [but he argued in the alternative based on the filed literature that] she meets the timing requirement of actual causation even if her onset was later than 48 hours." Pet'r's Ex. 19 at 3.

B. Petitioner's Expert, Uma Srikumaran, M.D.

Uma Srikumaran, M.D. is a board-certified orthopaedic surgeon and an associate professor at the Johns Hopkins University School of Medicine in the Department of Orthopaedic Surgery, Shoulder Division. Pet'r's Ex. 25 at 1, ECF No. 46-1. He received his undergraduate degree from Northwestern University and obtained his medical degree from Johns Hopkins. Pet'r's Ex. 38 at 1, ECF No. 50-2. Dr. Srikumaran then completed an internship and residency in orthopaedic surgery before obtaining master's degrees in business administration and public health, also from Johns Hopkins. *Id.* He has served as assistant team physician for the Baltimore Orioles and, in addition to teaching, now serves as the Shoulder Fellowship Director at Johns Hopkins, as Chair of Orthopaedic Surgery for the Howard County General Hospital, and as the Medical Director of the Johns Hopkins Musculoskeletal Service Line at the Columbia, Maryland site. *Id.* at 2.

Dr. Srikumaran has "published numerous articles in the field of shoulder surgery, [but he has] not published specifically related to shoulder injuries related to [v]accination [a]dministration [ ]." Pet'r's Ex. 25 at 1. His practice over the last five years includes "10–12 patients with shoulder dysfunction after vaccination[.]" *Id.* Overall Dr. Srikumaran sees "approximately 2500–3000 patients for shoulder issues and [performs] 400–500 shoulder surgeries annually." *Id.*

In support of his opinion that Petitioner suffered a Table SIRVA, Dr. Srikumaran went through the requirements in his expert report. *See id.* at 6–10. Dr. Srikumaran noted that Petitioner had fibromyalgia flares pre vaccination. *Id.* at 6. However, Dr. Srikumaran did not believe that Petitioner's post-vaccination symptoms were consistent with her pre-existing injury. *Id.* Specifically, Dr. Srikumaran stated that Petitioner's "fibromyalgia flares were documented to include the areas of the neck and radiating to the base of the skull, along with lower back [ ]." *Id.* (citing Pet'r's Ex. 5 at 3). Furthermore, Dr. Srikumaran noted that pre vaccination, Petitioner only suffered "mild decreased cervical spine ROM with lateral rotation bilaterally [ ]." *Id.* (citing Pet'r's Ex. 5 at 4, 7, 11, 15, 24, 28, 32, 36). Petitioner's June 13, 2017 complaint of radiating neck and elbow pain is explained by Dr. Srikumaran as "shoulder pathology [ ] affecting [Petitioner's] surrounding musculature and causing increased pain in the adjacent tissues of the cervical spine and upper arm to her elbow." *Id.* at 7.

Dr. Srikumaran also noted that Petitioner consistently related her shoulder pain to her vaccine, and her witness statements all corroborate an immediate onset of shoulder pain post vaccination. *Id.* Furthermore, "[t]here are no documents available to [Dr. Srikumaran] that would call into question [Petitioner's] statements and [her] very consistent medical reports." *Id.* at 9. In his experience, [t]he vast majority of patients do not have their pain (outside of acute traumas/emergency room situations) evaluated within 48 hours." *Id.* Dr. Srikumaran explained that many people believe that the pain will recede with time and "try several over the counter remedies for many weeks or months before seeking professional evaluation (particularly when they expert there is to be some pain as after any vaccination." *Id.* He also noted the costs of seeking medical

care and how a patient's pain tolerance level can impact when medical care is ultimately sought. *Id.*

Dr. Srikumaran shared the opinion of Respondent's expert that Petitioner's MRI findings are "consistent with degenerative conditions," but he noted that they "disagree on several points." *Id.* at 8. He noted that Petitioner's "MRI was obtained after [Petitioner] had received a second corticosteroid injection in the subacromial space." *Id.* Therefore, "[i]t is reasonable that a successful injection into the subacromial space given less than two weeks prior to an MRI would reduce inflammation in the bursal tissue to a level that was not easily detectable." *Id.* This chronology is in addition to a bursectomy, which indicates that bursitis "was thought to be causing or contributing to pain and inflammation." *Id.* Dr. Srikumaran argued that "the vast majority of the population in their 50s will have 'chronic degenerative conditions' in their shoulder that are readily detectable on MRI scans[,] and they are most likely to be asymptomatic." *Id.* Petitioner's symptoms were not explained by a chronic condition in Dr. Srikumaran's opinion. *Id.* Dr. Srikumaran asserted that "[v]accination did not cause these degenerative conditions, but [it] was the trigger that instigated inflammation of the surrounding structures and tissues, causing symptoms consistent with impingement syndrome (a term that is commonly used in cases of SIRVA injury." *Id.* at 8–9. He noted that "there were no other injuries or activities in this time period that provide an alternate explanation, i.e.[,] another trigger like a fall or unusual event . . . ." *Id.* at 9–10.

After Dr. Srikumaran characterized of Petitioner's injury as a Table SIRVA, he also noted that "the criteria for causation in fact are also met[.]" *Id.* at 11. He relied on the filed articles and echoed Dr. Colwell's explanation that injury results from "an immune mediated response of inflammation related to antigens injected into the bursal tissue, likely from poor technique related to various factors (site, needle choice, angle and location of injection, not accounting for patient size variation)." *Id.* Dr. Srikumaran asserted that Petitioner's injection site was "inadvertently near the bursa or rotator cuff tendon[, and this] led to a strong immune mediated inflammatory reaction, causing bursitis and tendinitis." *Id.* at 12. After reiterating the appropriate temporal relationship between Petitioner's vaccination and pain onset, Dr. Srikumaran briefly noted that Petitioner was asymptomatic pre vaccination. *Id.* He concluded that Petitioner's "current condition is well documented in the medical records[,] and the time course of events supports that she had a significant aggravation of a condition that existed prior to vaccination." *Id.*

The supplemental report issued by Dr. Srikumaran did not contain any new arguments. *See* Pet'r's Ex. 37, ECF No. 50-1. He repeated that Petitioner's change in symptom characterization between when she described her fibromyalgia neck pain pre vaccination and when she described her shoulder pain post vaccination was the key factor for his determination that Petitioner's shoulder symptoms were due to her vaccination rather than her fibromyalgia. *Id.* at 1. Dr. Srikumaran also again mentioned Petitioner's consistent account that her shoulder pain began immediately after her vaccination. *See id.* at 1, 5.

After acknowledging that "cervical spine pain and shoulder pain can be difficult to diagnose and differentiate from one another[,]" Dr. Srikumaran argued that "a complete consideration of the historical details, their timing, in conjunction with the associated exam and diagnostic test findings is critical for evaluation and management." *Id.* at 1. He explained that in

this case, "the most likely mechanism" explaining Petitioner's neck pain in June of 2017 is that Petitioner attempted to mitigate her shoulder pain "by adjusting [her] shoulder girdle[,]" leading to neck spasms and pain and "causing [her] neck condition (disc degeneration/arthritis) to become symptomatic or worsen." *Id.* at 3.

Dr. Srikumaran maintained his opinion that Petitioner's "symptoms of impingement improve and worsen over the course of her treatment[] and depend on medications and injections targeted at removing inflammation." *Id.* at 4. In support of his contention that Petitioner had bursitis, Dr. Srikumaran noted that the record did not include the MRI images, but only the report, which did not state whether Petitioner's bursa was abnormal or even mention it at all. *Id.* There is, however, a record of Petitioner's complete bursectomy, "indicating that there was a significantly inflamed bursa which the surgeon felt needed to be removed." *Id.*

C. Respondent's Expert, Paul J. Cagle, M.D.

Paul J. Cagle, M.D. is a board-certified orthopaedic surgeon and an assistant professor and associate program director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Resp't's. Ex. A at 1.[18] Currently, Dr. Cagle's practice "focuses on the shoulder, representing approximately 95% or more of the patients and pathology [he] treat[s]." *Id.* His professional memberships include the American Shoulder and Elbow Surgeons, the American Academy of Orthopaedic Surgeons, and the American Orthopaedic Association. *Id.*

In his initial export report, Dr. Cagle identified problems with Petitioner's "timing, the mechanism and actual injury." *Id.* at 2–3. He noted that "there is no medical record, except for her reporting, establishing a 48[-]hour link between the vaccination event and the onset of shoulder pain." *Id.* Dr. Cagle further noted that Petitioner does have medical records that document examinations "by two providers who did not document shoulder pain but did document a normal shoulder exam." *Id.* at 4. Specially, Dr. Cagle cited that Dr. Becker conducted a system review on December 1, 2016, including "a shoulder exam that demonstrates 5/5 shoulder strength in abduction, internal rotation and external rotation [ ]." *Id.* at 1 (citing Pet'r's Ex. 5 at 1–4).

Dr. Cagle's second point of contention is that "the actual injury mechanism [was] never establish[ed]." *Id.* at 3. He stated that Petitioner was diagnosed with shoulder impingement, but he argued that "the [June 30, 2017] MRI findings in this case are actually in stark contradiction to the published SIRVA literature." *Id.* Dr. Cagle explained that SIRVA patients have increased bursal fluid as evidence of local inflammation. *Id.* In Petitioner's case, there was "no significant joint effusion or bursitis, and there is notation of chronic shoulder conditions consisting of a chronic rotator cuff tearing and chronic labral tears [ ]." *Id.* (citing Pet'r's Ex. 2 at 23–24). Dr. Cagle reasoned that Petitioner's "MRI findings represent typical age[-]related degenerative change." *Id.* He cited several studies indicating that "people over the age of 50 years old can have asymptomatic rotator cuff tears[]" and that "demonstrate[] that over 50% of individuals with an asymptomatic rotator cuff tear will become symptomatic in an average of 2.8 years." *Id.* Dr. Cagle opined that it is "highly likely[,]" given that Petitioner is over 50, that she suffered from "an underlying rotator cuff tear that predated the injection[.]" *Id.*

[18] Respondent did not file Dr. Cagle's CV in this case, but he frequently submits expert reports on SIRVAs and similar injuries in the Program.

Lastly, Dr. Cagle argued that "there is no explanation as to what structure(s) was/were injured or how this injury occurred." *Id.* Dr. Colwell did not discuss overpenetration, and Dr. Cagle argued that Petitioner is "well within the safe weight range (77.7 kg on 1/26/17), it is not conceivable how a standard needled [sic] would have let to an overpenetration event." *Id.* at 4.

Dr. Cagle's supplemental report was specifically focused on onset and clinical presentation. *See* Resp't's Ex. B at 1–2. He disputed Dr. Colwell's description of Petitioner's complaints as consistent and noted that post vaccination, Petitioner "had a documented normal shoulder exam[.]" *Id.* at 1. Furthermore, Dr. Cagle opined that "it does not make any sense that [Petitioner] would selectively not mention [her shoulder pain] immediately after the injection but then mention it every time after [January 26, 2017]." *Id.* He did not find "support for the less than 48[-]hour time table necessary to qualify for a [Table] SIRVA." *Id.*

In direct response to Dr. Colwell's reliance on Petitioner's MRI results, Dr. Cagle noted that "Dr. [Colwell] selectively ignores the findings of AC joint arthrosis (joint degeneration) and glenohumeral arthrosis (joint degeneration)." *Id.* In doing so, Dr. Cagle argued that Dr. Colwell incorrectly attributed Petitioner's rotator cuff tendinosis to SIRVA, even in "the absence of a bursal fluid signal." *Id.* at 1–2. Dr. Cagle explained that an increase in bursal fluid is an indicator of the acute inflammation seen "in the SIRVA literature." *Id.* at 1. He concluded that "[w]ithout a significant bursal fluid increase, the logical interpretation of the MRI findings are that these are all consistent with chronic degenerative changes." *Id.* at 2.

Following Dr. Srikumaran's report, Dr. Cagle responded in a second supplemental report. Resp't's Ex. C, ECF No. 49-1. Dr. Cagle noted that Dr. Srikumaran attributed Petitioner's increased pain "in the adjacent tissues of the cervical spine and upper arm to her elbow[]" to her shoulder injury. *Id.* at 1 (quoting Pet'r's Ex. 25 at 7). He questioned why Dr. Srikumaran's theory "could[not] be reciprocal." *Id.* Dr. Cagle asserted that "[i]t is just as likely that pain in the cervical region could cause pain in the surrounding musculature of the shoulder." *Id.* He continued that "[f]ibromyalgia in the cervical [ ] region could have caused associated pain in the shoulder region[,]" and in this case, "[f]ibromyalgia is a [documented] preexisting condition that can explain the symptoms." *Id.*

Dr. Cagle also disputed Dr. Srikumaran's suggestion that Petitioner's cortisone injection "provided complete resolution of the bursal inflammation to a point that no trace of it was demonstrated on the MRI[.]" *Id.* at 2. He asserted that this line of reasoning does not account for "how a cortisone injection is capable of capable of clearing up all MRI signs of inflammation but simultaneously not improving clinical symptoms." *Id.* Dr. Cagle then explicitly stated that "[i]t is in conflict to state in one paragraph that inflammation in the subacromial space was alleviated by a cortisone injection and then subsequently to state that impingement syndrome (inflammation in the subacromial space) was present." *Id.* Finally, Dr. Cagle noted that Dr. Srikumaran did not address the shoulder exam done by Dr. Becker on December 1, 2016, which yielded normal results, in his analysis on Petitioner's shoulder injury onset. *Id.* at 3.

IV. Applicable Statutory Scheme

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table injury cases are guided by statutory "Qualifications and Aids in Interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited [ROM] occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced [ROM] are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, she may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table," or causation-in-fact, claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 300aa-13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344,

1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

In the seminal case of *Althen v. Sec'y of of Health & Hum. Servs*., the Federal Circuit set forth a three-pronged test to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen,* a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278–81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data

and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [ ] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *See* 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* (quoting *Althen*, 418 F.3d at 1280). In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685

F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Once a petitioner has established her prima facie case, the burden then shifts to Respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B). The Vaccine Act requires Respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* § 300aa-13(a)(2)(B). The factor unrelated must be the "sole substantial factor[;]" therefore, Respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354.

V. Discussion

In the present case, the parties are unable to agree on any material fact or legal conclusion, save that Petitioner's Tdap vaccination occurred on October 25, 2016. Petitioner maintains that she suffered a left-sided shoulder injury that satisfies the QAI criteria for a SIRVA. Alternatively, Petitioner also submitted evidence of causation through her expert reports and medical literature. Although not explicitly alleged, one of Petitioner's experts characterized Petitioner's shoulder injury as "a significant aggravation of a condition that existed prior to vaccination." Pet'r's Ex. 25 at 12. Dr. Srikumaran did not elaborate on this contention aside from conclusions that Petitioner meets the additional factors for significant aggravation. *Id.* Specifically, Dr. Srikumaran noted that Petitioner was asymptomatic prior to her vaccination and that her current condition is "well documented in the medical records[,]" establishing a clear "significant aggravation[.]" *Id.*

Dr. Cagle, however, disputed the characterization of the claim as on-Table, the timing of onset, and the nature of Petitioner's symptoms. He also argued that there is an alternate cause for Petitioner's symptoms that is a pre-existing condition. After a thorough review of the record, I find that Petitioner has not presented preponderant evidence of a Table claim because she is unable to satisfy the QAI criteria. However, Petitioner has submitted evidence of a theory of causation, a logical sequence of cause and effect, and an appropriate temporal relationship for an off-Table shoulder injury. I find that Petitioner has presented preponderant evidence that she suffered an off-Table injury to her left shoulder that was caused by the administration of her Tdap vaccine.

A. Table Claim

i. History of Pain, Inflammation, or Dysfunction

Petitioner underwent spinal surgery in 2007, and she also has a history of fibromyalgia, migraines, and seizures. Pet'r's Ex. 4 at 7. Petitioner's expert Dr. Srikumaran argued that Petitioner's pre-vaccination fibromyalgia pain is distinguishable from her alleged shoulder injury because her "fibromyalgia flares were documented to include the areas of the neck and radiating to the base of the skull, along with lower back [ ]." Pet'r's Ex. 25 at 6. In contrast, Petitioner reported that post vaccination, she suffered severe and intense pain in her left shoulder that "became [,] and [she] experienced weakness, throbbing and some numbness." Pet'r's Ex. 7 ¶ 2. Respondent's expert did not contend that Petitioner complained of shoulder pain during her pre-vaccination treatment for fibromyalgia, although ultimately, Dr. Cagle asserted that "[f]ibromyalgia is a preexisting condition that can explain [Petitioner's shoulder] symptoms." Resp't's Ex. C at 1. The first QAI criterion specifically refers to "history of pain, inflammation or dysfunction of the affected shoulder[.]" 42 CFR §100.3(c)(10). There is no evidence that Petitioner suffered from left shoulder pain prior to vaccination. Therefore, I find that Petitioner has satisfied the first of the QAI criteria that she had no pre-vaccination history of pain, inflammation, or dysfunction of the affected shoulder.

ii. 48-Hour Symptom Onset

While it is true that Petitioner consistently related her shoulder pain to her October 25, 2016 Tdap vaccination, it is also true that she did not report her injury to a medical provider for approximately three months post vaccination. Petitioner's experts presented opinion evidence and medical evidence to explain why a patient would wait for such an extended period of time to seek treatment for the type of severe pain that Petitioner complained of. Petitioner's personal and witness affidavits are also compelling evidence that Petitioner's pain was related to her vaccination. However, despite Petitioner's failure to mention her shoulder pain to her PCP and neurologist during regularly scheduled visits related to her pre-existing conditions, Petitioner's medical records are not silent on the condition of Petitioner's shoulder during this time. Dr. Cagle noted that during Petitioner's visit with Dr. Becker on December 1, 2016, Petitioner underwent "a shoulder exam that demonstrate[d] 5/5 shoulder strength in abduction, internal rotation and external rotation." Resp't's Ex. A at 1 (citing Pet'r's Ex. 5 at 4). That record noted that Petitioner had decreased ROM (mildly *to either side*)." Pet'r's Ex. 5 at 4 (emphasis added). Dr. Becker also noted that Petitioner reported "no joint pain, joint stiffness, [and] no weakness of muscles or joints[.]" *Id.* at 3. In her affidavit, Petitioner explained that these routine medical visits are only fifteen minutes, that "[t]he pain in [her] shoulder was never mentioned during [their] time together, and that Dr. Becker did not conduct an examination of [her] left shoulder on that day." Pet'r's Ex. 11 ¶ 3. Petitioner's account of her December 1, 2016 medical visit with Dr. Becker is in direct contradiction with the extensive and contemporaneous treater record. Often, petitioners are able to show that medical records contain inaccuracies. This is especially true with respect to the medical and patient history parts of the record, which are often a cut-and-paste from prior visits, and the complaint history, which can be a series of boxes hastily checked post visit. This case contains the results of an examination that Petitioner attested never occurred. Furthermore, Petitioner suggested that her report to Dr. Becker that she was experiencing no joint pain was, unintentionally or otherwise, fabricated. In evaluating whether elements of a claim have been met, medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. *Cucuras*, 993 F.2d at 1528.

Medical records created contemporaneously with the events they describe are generally

trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) (citing *Cucuras*, 993 F.2d at 1528). This is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020). However, there is no presumption that medical records are accurate and complete as to all the patient's physical conditions. *Kirby*, 997 F.3d at 1383. Where there are inconsistencies, special masters are within their discretion to award contemporaneous medical records greater weight than later conflicting testimony. *See Cucuras*, 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master").

Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened

during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as hearing testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

In the present case, I must weigh Petitioner's presented lay witness testimony: her personal affidavit and the affidavits of her family members, against the December 1, 2016 medical record from Dr. Becker's office. Petitioner alleged that she failed to recount her pain to Dr. Becker. However, that still does not explain the results of his physical exam, which are inconsistent with Petitioner's account of excruciating pain such that "the next day after receiving the shot, [she] was unable to lift or move [her] arm at all without pain." Pet'r's Ex. 11 ¶ 2. Furthermore, it is surprising that Petitioner would be experiencing that degree of pain during an exam and not relay her condition to the doctor in real time. This is especially surprising given that Petitioner reported four "episodes of pain and tingling" between her neck and her skull and in her lower back related to her fibromyalgia during this appointment. *See* Pet'r's Ex. 5 at 3. There is no assertion that Dr. Becker failed to document Petitioner's reported condition or that there was an accounting of nonexistent symptoms. That leaves Petitioner's faulty recollection of the events. *See LaLonde*, 110 Fed. Cl. at 203–04. I do not see how this record can be reconciled with Petitioner's described level of shoulder pain that began several weeks prior to this visit and continued beyond her filing of a VAERS report on December 27, 2016. Petitioner stated that she filed the VAERS report because she wanted to "notify someone in the government about the debilitating pain that the shot had caused." Pet'r's Ex. 11 ¶ 2. At that point, Petitioner relayed her shoulder pain back to her vaccination, and she was consistent from that point on. There is therefore preponderant evidence that sometime between December 1 and 27, 2016, Petitioner was experiencing severe shoulder pain that she attributed to her vaccination. Petitioner has not established by preponderant evidence that she experienced pain with the specified time-frame of 48 hours. However, Petitioner has established that she experienced her shoulder pain, documented it, and related it back to her vaccination within two months post vaccination.

iii. Nature of Symptoms

Prior to her vaccination, Petitioner was being treated by her neurologist, Dr. Becker, for migraines and seizures. *See generally* Pet'r's Ex. 5. She was also being treated for fibromyalgia. *See* Pet'r's Ex. 4 at 7.[19] These ailments led to complaints by Petitioner of headaches, back pain, and neck pain, but there is no indication in the record pre vaccination that she was treated for shoulder pain. Post vaccination, Petitioner reported to her orthopaedist on January 26, 2017, that in addition to her shoulder pain, she was suffering from back pain. Pet'r's Ex. 2 at 7. Notably, she was assessed with left shoulder impingement. *Id.* at 27. During a physical therapy session on June 13, 2017, Petitioner described the pain "radiating into her neck and into her neck and down into her elbow." *Id.* at 17. This is consistent with Dr. Srikumaran's opinion that Petitioner's "shoulder pathology is affecting the surrounding musculature and causing increased pain in the adjacent

[19] It does not appear that Dr. Becker generally treated Petitioner's fibromyalgia. *See generally* Pet'r's Ex. 5.

tissues of the cervical spine and upper arm to her elbow." *See* Pet'r's Ex. 25 at 7. Petitioner had complaints of pain in areas other than her shoulder, and these complaints were specifically connected to her shoulder pain. Therefore, she is unable to establish by preponderant evidence that her pain is limited to the shoulder where she received her injection.

iv. Lack of Alternative Condition

The last QAI criterion prohibits compensation for a Table SIRVA if any alternative condition is present that could explain Petitioner's symptoms. Petitioner is also unable satisfy this requirement. After a review of Petitioner's medical records, affidavits, expert reports, and medical literature, I find that there is preponderant evidence that Petitioner's post-vaccination symptoms could be explained by fibromyalgia. Fibromyalgia is defined by *Dorland's Illustrated Medical Dictionary* as "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." *Dorland's* at 696. Petitioner's fibromyalgia would explain Petitioner's shoulder symptoms by nature of the condition. In fact, Drs. Srikumaran and Cagle agreed that it is often difficult when treating patients to discern whether cervical pain or shoulder pain came first, as the two areas are connected and interrelated. While it is not clear that Petitioner's shoulder pain was caused by her fibromyalgia, the existence of her fibromyalgia precludes her from establishing that she suffered from a Table SIRVA.

Petitioner has not presented preponderant evidence that she suffered from a Table SIRVA. Table claims carry a presumption because they are unhindered by previous similar injury, additional symptoms indicative or other conditions, and timing concerns. They are streamlined, and often resolve without medical expert reports or opinions to rule out other diagnoses. In cases where other issues are present, cases proceed more deliberately. It is Petitioner's burden to overcome those complications using the parameters set forth in *Althen.* While it is true that the QAI criteria set the parameters for a Table claim, failure to meet the standard for presumption does not disqualify Petitioner's assertion that she did in fact suffer a vaccine-caused shoulder injury, notwithstanding her fibromyalgia diagnosis. In this case, Petitioner has presented evidence that her shoulder injury was caused-in-fact by her vaccination. Therefore, I will complete an *Althen* analysis.

B. Causation-in-fact

i. *Althen* Prong One: General Causation Theory

SIRVA is a well-known phenomenon in the Program, but petitioners must present a causation theory in all off-Table cases. Dr. Srikumaran relied on the filed articles and echoed Dr. Colwell's explanation of the mechanics of a shoulder injury caused by vaccination. He concisely summarized that injury results from "an immune mediated response of inflammation related to antigens injected into the bursal tissue, likely from poor technique related to various factors (site, needle choice, angle and location of injection, not accounting for patient size variation)." Pet'r's Ex. 25 at 11. Dr. Colwell provided medical literature support via the 2010 Atanasoff et al. article that "provides support for the theory that antigenic material from the vaccine that is injected into synovial tissues results in an immune mediated inflammatory reaction." Pet'r's Ex. 19 at 2 (citing Pet'r's Ex. 21 at 1). The Bodor and Montalvo article also cautioned against vaccinations "in the upper third of the deltoid muscle," and they identified subacromial bursitis, bicipital tendonitis,

and adhesive capsulitis as consistent a diagnosis of "vaccination-related shoulder dysfunction." Pet'r's Ex. 20 at 3. Dr. Cagle did not directly contradict this reasoning. *See generally* Resp't's Exs. A–C. Petitioner has presented preponderant evidence that the Tdap vaccine can cause an off-Table shoulder injury related to vaccination, and she has therefore satisfied prong one of *Althen*.

ii. *Althen* Prong Two: Specific Causation

Petitioner stated that she believes her Tdap vaccine was administered in her upper left shoulder, and her husband and sister asserted that Petitioner reported that her Tdap vaccine was administered higher in her left arm than the vaccines she received in her right arm. Pet'r's Ex. 7 ¶ 1; Pet'r's Ex. 13 at 1; Pet'r's Ex. 15 at 1. Petitioner recounted increasing pain in her left shoulder that decreased her range of motion and made it impossible to perform everyday tasks. *See* Pet'r's Ex. 7 ¶ 6. Petitioner did not report her pain immediately to her doctor, and her medical record documents a normal shoulder exam approximately five weeks post vaccination. However, Petitioner did begin to seek treatment for her shoulder pain, and she consistently described her injury as vaccine-caused, even submitting a VAERS report. Her treaters administered steroid injections, and Petitioner underwent physical therapy based on a shoulder impingement diagnosis before she was referred for shoulder surgery. Although Petitioner's treaters did not attribute her injury to her vaccination, neither did they attribute it to fibromyalgia. Her symptoms and course of treatment are consistent with a shoulder injury related to vaccination. Dr. Cagle identified preponderant evidence in the record that Petitioner suffered wear-and-tear injury from old age. However, there is nothing in the record that suggests that her osteoarthritis was symptomatic prior to her vaccination. Additionally, there is no evidence presented that Petitioner could not suffer from osteoarthritis that was further irritated by her vaccine. Petitioner has presented preponderant evidence that her vaccine was administered higher in the upper left arm, near the bursa or rotator cuff tendon leading to an inflammatory reaction and pain.

Although Dr. Srikumaran briefly referenced significant aggravation, he only highlighted that Petitioner was asymptomatic pre vaccination and that, despite no prior history of shoulder complaints, Petitioner required surgery post vaccination. These facts are not enough to establish a significant aggravation claim. Petitioner's but-for causation claim is stronger, given that Petitioner is alleging, based on the pleadings and the injury mechanism, that the new symptom/injury was caused by the vaccine injection.

iii. *Althen* Prong Three: Temporal Relationship

During the Table claim analysis, I found that Petitioner has not presented preponderant evidence that her injury manifested within 48 hours of her vaccination. The record contains preponderant evidence that Petitioner was examined by a treater approximately five weeks post vaccination, and her neurologist found normal motor strength, abduction, and rotation. Pet'r's Ex. 5 at 4. Furthermore, the medical record noted that Petitioner did not report joint pain. *Id.* at 3. It is possible that Petitioner could have been experiencing pain at that time that did not rise to the level of manifesting during her exam, although this would be inconsistent with Petitioner's description of her pain as severe. It is also possible that as Petitioner stated, she did not discuss her shoulder pain at that time because she was there to treat other conditions. She described her other conditions as serious, but it is curious why her inability to "do any of [her] daily duties," including cooking,

cleaning, dressing, and caring for her disabled son would not be considered serious. *See* Pet'r's Ex. 7 ¶ 6. As discussed earlier, I find that Petitioner presented preponderant evidence that she was experiencing shoulder pain within two months of her vaccination. However, the medical record does not support severe shoulder pain prior to her December 1, 2016 doctor's visit. The Arias article noted that although six of eight of the patients in the study experienced pain within the first four to seven days, two patients reported their pain to medical providers within two months. Pet'r's Ex. 23 at 3. Dr. Cagle did not dispute that off-Table SIRVA pain could manifest within two months post vaccination. The Arias article also describes that pain as increasing in severity. *Id.* These cases are more consistent with Petitioner's, where she described immediate pain, but the record does not provide contemporaneous evidence of that until several weeks later, within two months. Petitioner has presented preponderant evidence in the form of medical literature that explains how the timing and presentation of her shoulder pain related to vaccination is appropriate.

C. Alternative Causation

Dr. Cagle suggested that Petitioner's fibromyalgia could be the cause-in-fact of Petitioner's shoulder's symptoms. *See* Resp't's Ex. C at 1. However, Dr. Cagle did not adequately explain the shift in Petitioner's fibromyalgia pain from her neck and back to her left shoulder. He also did not identify in the record where Petitioner conflates her fibromyalgia pain with the shoulder pain that she alleges is vaccine-caused. There is much debate between the experts on the significance of a lack of bursal fluid or signs of inflammation. Dr. Cagle argued that without an increase in bursal fluid, Petitioner lacks the necessary signs of post-vaccination inflammation. However, he did not address Petitioner's bursectomy, which provides a strong indication of bursal abnormality. There also appears to be a chicken versus egg conundrum in terms of the shoulder pain exacerbating cervical spine pain or vice versa. Dr. Cagle implied that if Petitioner has fibromyalgia or any chronic diffuse pain condition, she cannot ever establish that post-vaccination shoulder pain is related to vaccination. In this case, I find that Petitioner was able to establish that she experienced symptoms that are not consistent with her previously reported fibromyalgia pain.

Another potential cause identified by Dr. Cagle was the natural wear-and-tear of osteoarthritis. Again, he did not provide explanation as to why Petitioner's asymptomatic osteoarthritis became painful and severe enough to require surgery shortly after she received a vaccination. I do not find that the asserted alternative causes fit Petitioner's clinical picture by a preponderant standard. Therefore, I do not find that Respondent has overcome Petitioner's causation prima facie case.

VI. Conclusion

After considering the entire record, Petitioner has established by preponderant evidence that she suffered from an off-Table shoulder injury as the result of her October 25, 2016 Tdap vaccination. Accordingly, Petitioner is entitled to compensation. This case shall proceed to damages.[20]

IT IS SO ORDERED.

[20] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master